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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,485	05/25/2001	Scott D. Feighner	20251P	8604

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,485	FEIGHNER ET AL.	
	Examin r	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE f this communication appears on the cover sheet with the corresp ndenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) 7 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/25/01, 11/0303*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I claims 1-6 and 8 drawn to a G protein coupled receptor disclosed in SEQ ID NOS:2-5 and method for determining whether a ligand is capable of binding a motilin receptor on 11/3/03 is acknowledged. The typographical error highlighted by Applicant is has been corrected. Claim 8 has been included in Group I, and claim 2 removed from Group I and placed in Group II. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. The requirement is still deemed proper and is therefore made FINAL.

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Objections

The disclosure is objected to because of the following informalities:

3. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 3, Applicant has written "BRIEF DESCRIPTION OF THE FIGURES"

Appropriate correction is required.

4. Page 1, contains "xxxxx" on lines , 5, 8, and 11. The significance of "xxxxx" is not clear. The "xxxxx" should be amended or removed from the disclosure.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-6 and rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-6 recite a motilin receptor but do not recite that the receptor is isolated or purified. The claims, as currently recited, encompass these naturally occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified receptor to overcome this rejection.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 8 are indefinite because the name motilin receptor does not provide any structural limitations, and the metes and bounds of the claim cannot be determined. It is unclear what structure encompasses a motilin

receptor. It is suggested, to overcome the rejection, motilin be identified by SEQ ID NO.

Claims 4 is indefinite because the motilin receptor does have the nucleic acid of SEQ ID NO:2, it is encoded by the polynucleotide, the sequence of which is disclosed by SEQ ID NO:2.

Claims 6 is indefinite because the motilin receptor does have the nucleic acid of SEQ ID NO:4, it is encoded by the polynucleotide, the sequence of which is disclosed by SEQ ID NO:4.

7. ***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a motilin receptor having the amino acid sequence disclosed in SEQ ID NOS:3 and 5, encoded by the polynucleotide having the nucleic acid sequence disclosed in SEQ ID NOS 2 and 4, respectively, and method for determining whether a ligand is capable of binding to said motilin receptor does not reasonably provide enablement for other motilin receptors or for method for determining whether a ligand is capable of binding to other motilin receptors. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification has disclosed the polynucleotide of SEQ ID NO:1, which encompasses SEQ ID NOS 2 and 4, encoding splice variants of a motilin receptor disclosed in SEQ ID NO:3 and 5. While the person of ordinary skill in the art would, in light of the specification be able to isolate and use the motilin receptor disclosed in SEQ ID NOS 2 and 4, there is no disclosure in the specification or prior art that a other receptors or variants generally classified as motilin receptors can be isolated and used without undue experimentation. The name motilin receptor does not provide any structural limitations. It is unclear what structures encompass a motilin receptor, which would have the functionality of the polypeptide encoded by the nucleic acid of SEQ ID NOS:2 and 4. The scope of the claims, which encompass other peptides, apart from those disclosed in SEQ ID NOS 3 and 5, are not enabled by the disclosure. The disclosure does not teach how to make or identify such variants, or to use a commensurate number of the variants , which did not share all the functional properties encompassed by the peptide of SEQ ID NOS:3 and 5. Due to the large quantity of experimentation necessary to identify the polypeptides encompassed by claims 1, 2 and 8, the lack of direction/guidance presented in the specification regarding the production, identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of SEQ ID NOS:2-4 are also encompassed by the claim), and the breadth of the claim which fail to recite

critical structural features of the invention required for activity (i.e. structure and function relationship), undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

Claim Rejection 35 USC § 112, 1st paragraph (Written Description)

8. Claims 1, 2 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are claims 1, 2 and 8 are directed to a motilin receptor and method for determining whether a ligand is capable of binding to a motilin receptor.

The name motilin receptor does not provide any structural limitations and the name motilin receptor does not automatically infer a functionality. It is unclear what structure is encompassed by a motilin receptor. The claims encompass receptor variants of the protein named a motilin receptor, said variants may be completely unrelated, structurally and functionally to the protein of a motilin receptor.

The claims, as written, encompass polypeptides, which may vary substantially in length and also in amino acid composition. The instant disclosure of a polynucleotide of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:3 and 5 does not adequately describe the scope of the use of the claimed genus, which encompasses a substantial variety of subgenera including, proteins, variants of said proteins, chimeric constructs, fusion constructs, which may be

completely, unrelated structurally and functionally to the polypeptide of SEQ ID NO:3. and 5 A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. For example, what regions of a motilin receptor contain a definitive structural feature required for protein function? The specification proposes to discover other members of the genus by using screening assays and techniques involving probes, primers, hybridization. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the proteins encompassed. No identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Since the disclosure fails to describe the

common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific a polypeptide, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe, enable and use the genus as broadly claimed. The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. It is acknowledged that the skill of the artisan in the molecular biology art is high. However, in the current instance, **there is no clear evidence of the critical special technical feature of the polypeptides or how the critical special technical feature encompassed by the genus claimed relates to function.** Because of the lack of guidance in the prior art and current application, one skilled in the art could not predict if the variants have the same activity as the protein disclosed in SEQ ID NO:3 and 5. The receptor protein may bind motilin but have a completely different function to that of the protein disclosed by SEQ ID NO:2 and 4. Further the claims do not recite an activity for the claimed motilin receptor.

The skilled artisan cannot envision the detailed chemical structure of the encompassed compounds and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of

the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid or polypeptide is itself is required. See *Fibers v. Revel*, 25 USPQ d. 1601 at 1606 (CAFC 1993) and *Amen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative

number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Therefore the specification fails to disclose the activity of the claimed genus of polypeptides/polynucleotides, the critical special technical feature of the polypeptides/polynucleotides or how the critical special technical feature encompassed by the fragments and variants of claimed motilin receptor to function.

Further method of using claimed motilin receptor is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by McKee et. al. (See IDS McKee et. al., Genomics, Viol. 46, 426-434, 1997).

McKee discloses GPR 38 receptor, which is inherently a motilin receptor, thereby meeting the limitations of claims 1 and 2, absent evidence to the

contrary. McKee discloses GPR 38 receptor, which has 100% query, match to SEQ ID NOS: 3 and 5 of instant application, thereby meeting the limitation of claims 3-6, absent evidence to the contrary.

No claim is allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi NSB
Art Unit 1646
February 9, 2004

Michael D. Pak
MICHAEL PAK
PRIMARY EXAMINER